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# Cognitive processes as integrative component for developing expert decision-making systems: A workflow centered framework

Ashis Jalote-Parmar [a,*], Petra Badke-Schaub [a], Wajid Ali [b], Eigil Samset [b]

[a] Faculty of Industrial Design and Engineering, Delft University of Technology, Landbergstraat 15, 2628 CE Delft, The Netherlands
[b] University of Oslo, The Interventional Centre, Rikshospitalet, Sognsvannsveien 20, 0027 Oslo, Norway

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ABSTRACT

The development of expert decision-making systems, which improve task performance and reduce errors within an intra-operative clinical workspace, is critically dependent on two main aspects: (a) Analyzing the clinical requirements and cognitive processes within the workflow and (b) providing an optimal context for accurate situation awareness through effective intra-operative information visualization. This paper presents a workflow centered framework and its theoretical underpinnings to design expert decision-making systems. The framework integrates knowledge of the clinical workflow based on the requirements within the clinical workspace. Furthermore, it builds upon and integrates the theory of situation awareness into system design to improve decision-making. As an application example, this framework has been used to design an intra-operative visualization system (IVS), which provides image guidance to the clinicians to perform minimally invasive procedure. An evaluative study, comparing the traditional ultrasound guided procedure with the new developed IVS, has been conducted with expert intervention radiologists and medical students. The results reveal significant evidence for improved decision-making when using the IVS. Therefore, it can be stated that this study demonstrates the benefits of integrating knowledge of cognitive processes into system development to support clinical decision-making and hence improvement of task performance and prevention of errors.



## 1. Introduction

To develop expert systems, that provide appropriate decision-making support for the clinician at the right time [1–3], it is required to ensure that the information content and presentation is corresponding to the clinicians' information processing activities. Significant research in the area of medical informatics points to the importance of understanding cognitive processes to support human centered development of expert decision-making systems for complex workspaces [4–9]. Cognitive research investigates psychological processes during cognitive activities such as problem solving and decision-making. Empirical studies illustrate the benefits of including cognitive theories into system design to develop information systems, which lead to safer working environments and prevention of errors. Recent examples of such web based systems in the clinical workspace are computer based patient record systems [10], knowledge management systems for bio-medical engineering [11], computer based training systems in pathology [7], and anesthesiology training [9].

The introduction of new clinical techniques such as minimally invasive surgeries (MIS) has led to several technological innovations in the operation theatre [12]. However, inadequate information transparency, limited access, and poor visualization, compel the clinicians to rely on advancements in medical imaging technology, which promise to improve task visualization and navigation during interventions. These limitations in MIS are constantly giving rise to new research and development of activities in the area of expert decision-support systems. Such expert systems are providing real-time image guidance and task automation [12,13] while the clinician is performing the task (intra-operatively). The theoretical assumption is, that the expert systems should improve decision-making in dynamic workspaces by enhancing situation awareness of critical information related to the clinical workflow [14,15]. The term *clinical workflow is defined as the clinical problem solving process which is determined by the task boundaries, in terms of possibilities and limitations, within the clinical workspace in the three phases: before (pre-operative), during (intra-operative) and after (post-operative)* [16].

Reviewing the literature on recent technological development, it is obvious that aiming at the design of expert systems and pursuing a human centered approach involves major deficiencies with respect to the following issues:

* Corresponding author. Fax: +31 15 2787179.
*E-mail addresses:* ashisjalote@yahoo.com, a.jaloteparmar@tudelft.nl (A. Jalote-Parmar).

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(1) The current trends in the development of decision-support systems are mainly focused on applying workflow technology as a mean to optimize processes in the clinical workspace such as, component interaction [17] and imaging data automation [18,19]. However, the critical issue concerning the development of expert systems is not to automate clinical tasks by using workflow technology but to develop technologies that assist the clinical workflow. Consequently, technologies that are being developed are still driven by technological workflow rather than clinical workflow.

(2) The development of visualization support tools such as augmented reality [20], pre-operative planning [13] and fusion imaging [12] are often centered around introducing new technologies in the clinical workspace [3,16]. There is a rare evidence that sufficient understanding of clinical requirements is integrated in the early technology development phase [21]. As a consequence solutions are often more influenced by the latest technological trends rather than required by the clinicians [5]. The introduction of such technology may even lead to an increase in cognitive load rather than decreasing it, resulting in low performance and clinical errors. For example, the use of augmented reality head mounted displays (AHMD) [22] in the intra-operative clinical workspace seems to increase the cognitive load on the clinician. The problem with AHMD is that they require adapting to two ways of visualization at the same time; one which is the visualization provided via AHMD and the other during the clinical task itself. Although, the same technology may have it's benefits if the technology is integrated in the planning stage rather than the intra-operative stage.

To avoid a technology push into the clinical workspace, and develop solutions that support decision-making, requires a workflow centered development. The paper addresses these requirements focusing on the following two research questions:

- *How can the knowledge of the clinical workflow be included into the system development cycle to provide a foundation for designing expert decision-making systems?*
- *To what extent do expert systems, developed on the knowledge of the clinical workflow, aid in decision-making and improving the performance of the clinicians by preventing errors?* In this paper, the term clinician is referred for the expert such as, surgeons and intervention radiologists who perform the MIS procedures.

The existing ISO [23] standardized human centered development cycle outlines the standard phases of product development. However, this cycle lacks in incorporating or suggesting theoretical underpinning necessary to tackle developmental issues in complex work domains. Especially in the development of expert systems for clinical workspace, where complexity is determined by a lack of transparency, unpredictability of events [24] and low tolerance for errors [25]. Here the development of expert systems, which provide real-time image guidance to clinicians, requires the knowledge of expert decision-making in naturalistic decision-making environments [26]. To support system development this knowledge must be investigated and incorporated in various stages of the development cycle. Recent research has also illustrated a methodology to integrate theories from cognitive science such as, distributed cognition into the human centered design cycle for designing web based knowledge management systems [11].

This paper presents a workflow centered framework, which assists in developing expert systems for complex workspaces. The framework integrates a previously developed workflow integration matrix [16] into the development cycle to assess the requirements within the clinical workflow. The framework builds upon the theory of situation awareness, which outlines three cognitive processes as basic elements of decision-making: perception, comprehension and action plan. These processes are integrated into design and evaluation of the system to improve information visualization as the primary basis for supporting situation awareness. As an example, this paper illustrates how this framework can be applied in order to develop an expert decision-making system guiding minimally invasive procedures.

The organization of the paper is as follows: Section 2 explains the application of the development of the workflow centered framework, which has been applied to build up an intra-operative visualization system (IVS). Section 3 describes the design of the IVS prototype developed to provide image guidance for a selected MIS: radiofrequency ablation (RFA). Section 4 describes the experimental setup of the evaluative study that compares the performance of expert intervention radiologists and medical students while executing RFA using the two systems: IVS and the conventional ultrasound guided intervention. Section 5 describes the results of the evaluation study. The paper concludes with guidelines for the development of expert decision-making systems and with some comments on future implications of the framework.

## 2. A workflow centered development framework

In this section, we describe the application of a workflow centered framework by designing an intra-operative visualization system (IVS). IVS is an expert decision-making system, which provides real-time (intra-operative) image guidance to the clinicians while performing a minimally invasive procedure called radiofrequency ablation (RFA). The workflow centered development framework was generated to aid the development of expert decision-making systems for the multidisciplinary European Union project ARIS*ER (Augmenting Reality in Surgery) [27]. IVS has been developed together in collaboration with a multidisciplinary team including clinicians, technology developers, and a HCI designer.

The framework integrates cognitive processes in different phases of the human centered development cycle, which are: specify context of use, analyze requirements, design prototype and evaluate prototype of the system (see Fig. 1). This development cycle is followed by assessing the requirements within the clinical workspace and integrating the knowledge of the clinical workflow. Furthermore, the framework is built upon the theory of situation awareness [14], which is regarded as the theoretical backbone for improving information visualization in system design. Taking into account the complexity of the developmental process the involvement of a multidisciplinary team is needed. Therefore, this framework also considers the issue of sharing the requirements and knowledge of the surgical and developmental processes within a development team. The following section explains the application of the framework to develop IVS.

### 2.1. Phase 1: Specify context of use

In the initial phase of the development of any tool or expert system it is necessary to identify the user and specify the context in which the system will be used. As a development case an upcoming minimal invasive surgery (MIS) called, radiofrequency ablation (RFA) was selected. This selection was made by conducting interviews ($n = 10$) with surgeons and intervention radiologists performing RFA. These interviews were conducted at national hospitals in Norway and The Netherlands. RFA involves the use of radiofrequency needle to ablate cancerous tumors. Surgeons or intervention radiologists mainly perform RFA either laproscopically or percutaneously. Percutaneous approach of RFA was selected for developing an intra-operative visualization system. In this approach the RF needle is inserted through the patient skin to ablate the tumor in the liver. The key findings from the interviews are summarized below:

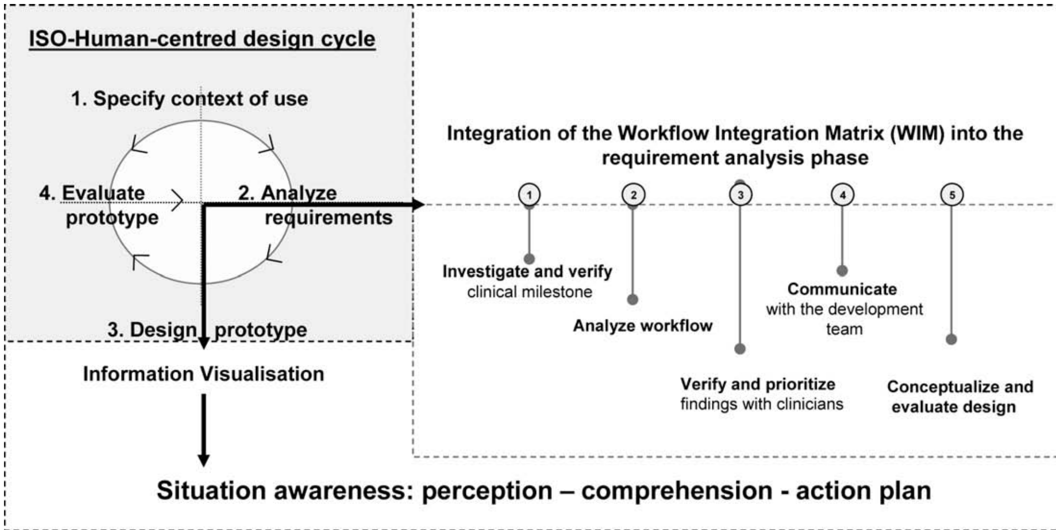


**Fig. 1.** Workflow centered development framework.

(a) Percutaneous RFA was described to be technically more advantageous over laparoscopic RFA. (b) Percutaneous RFA is a recent and complex MIS procedure requiring specialized skills. Therefore, the experts performing this procedure are still limited in number. Both, our findings and recent clinical studies [28] indicate that with better image guidance the clinical acceptance of this procedure can be improved. Currently, percutaneous RFA is mainly conducted by intervention radiologists, and is conventionally conducted with the guidance of ultrasound (US) imaging. However, well known drawbacks of US imaging, such as variable sound waves caused by nature of different tissues, add confusion and hence limit its value [28]. (c) A lack of adequate intra-operative visualization systems has caused failures in percutaneous RFA, causing procedures to be repeated [29]. These failures are due to unablated cancerous cells of the tumor, newly detected tumors and missed tumors [29].

## 2.2. Phase 2: Analyze requirements

The requirement analysis is the process of analyzing the clinical workflow in order to identify the clinical processes, problems, and requirements. Analyzing requirements also involves interfacing the clinical requirements with possible technological solutions. To facilitate this phase a previously developed framework called Workflow Integration Matrix or WIM [16] has been incorporated. This framework is build upon the theory of problem solving in complex workspaces and cognitive task analysis [30]. WIM consists of two main components, the current workflow and the future workflow. The *current workflow* allows the task decomposition of the three intervention phases (pre-operative, intra-operative, post-operative). The *future workflow* creates a bridge between the current clinical workflow and the future technological solutions. It includes a task-based summary of the clinical and technological requirements to create concept storyboards. The detailed explanation of the components of WIM framework can be seen in Appendix 1.

The requirement analysis for developing IVS has been divided into five stages which are described as follows:

### 2.2.1. Investigate and verify clinical milestones

Clinical milestones are critical steps, which have to be performed in order to complete the clinical procedure. In order to investigate the clinical milestones, a focus group with interventional radiologists ($n = 8$) practicing RFA was conducted. A HCI designer in collaboration with an intervention radiologists moderated this session. During the session the participants were asked to reflect and discuss problems, which occurred during the RFA procedure. The session revealed that six clinical milestones have to be performed in order to complete the RFA procedure. As an example, two main clinical milestones identified in the RFA procedure have been mapped on the *x*-axis of WIM (see Fig. 2) "*Identification of the target tumor*" and "*Entry and placement of the needle*".

### 2.2.2. Clinical workflow analysis

WIM was applied to analyze the RFA workflow. RFA procedures were observed ($n = 12$) in national hospitals of Norway and The Netherlands. These observations were conducted by a HCI designer by observing the clinicians in the three phases (pre-intra-post). The task boundaries in the current workflow of WIM were used to categorize and document the observations conducted in the clinical workspace. Each task boundary on the WIM *y*-axis is described as a parameter, which determines the problem solving process of the clinician. Task boundaries aid in accessing the information needs corresponding to the clinical milestones. For the designer the information is needed to reflect on several dimensions of information requirements and thus to gain understanding of clinical requirements. The observations related to each task boundary (Appendix 1) in each phase were semantically grouped and documented on the WIM framework. Fig. 2 illustrates a part of the RFA workflow analysis for the following two selected clinical milestones 3 and 4.

- Clinical milestone 3 (CM-3). In Fig. 2 the *x*-axis illustrates the clinical milestone 1: *Identification of the target tumor during the US intervention*. In the corresponding task boundary on the *y*-axis the *goal* of this milestone is explained as: *identify the target tumor with intra-operative ultrasound and compare it with the one planned to be ablated in the pre-operative CT*. Several patients have multiple hemagiomas or malignant tumors in the liver [31,32]. Recent clinical studies have shown that one of the errors in the RFA procedure is the ablation of unintended tumours [29]. To treat the tumors clinicians often decide on combining the RFA treatment with liver resection. In such a case during the pre-operative planning, one of the target tumors is selected for RFA treatment. The imaging modality used during pre-operative

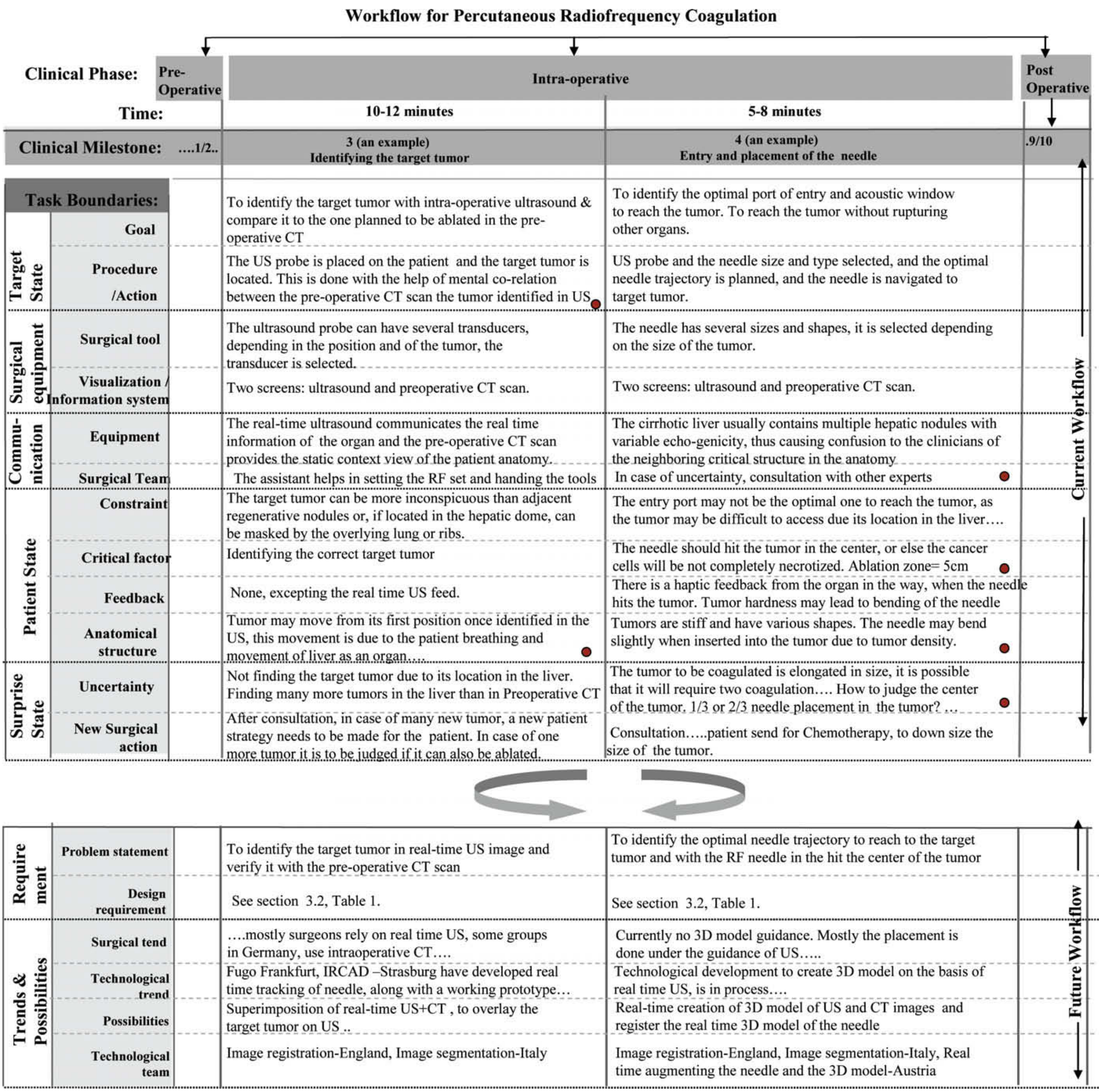


**Fig. 2.** Workflow of Percutaneous radiofrequency ablation (RFA).

planning is either a computerized tomography (CT) scan or a magnetic resonance imaging (MRI) scan. Another corresponding task boundary – *procedure* can be understood as: *the US probe is placed on the patient and the target tumor is identified. This is done with the help of mental co-relation between the pre-operative CT scan and the tumor identified in intra-operative US*. The difficulty arises due to two main reasons: First, the current imaging modalities do not support the transfer of the planning data into the intra-operative clinical phase. As a consequence, the necessary information is scattered and the clinician relies on creating a mental model by mentally superimposing the two images [33,34]. Second, identifying the correct tumor in US is itself a very challenging clinical task, due to the limitation of imaging modality. The cirrhotic (diseased) liver usually contains multiple hepatic nodules having different tissue properties that creates variable echo-genecity. Echo-genecity in US image is caused due to sound resonance that is effected by different tissue properties which create noisy data. Noisy data adds ambiguity in identifying the correct tumour in the US image leading to uncertainty in decision-making.

- Clinical milestone 4 (CM-4). In Fig. 2 another clinical milestone: *choosing the right trajectory and navigating the needle to the centre of the tumor* is described. In the corresponding task boundary on the *y*-axis, the *goal* of this milestone is explained as: *to identify the optimal port of entry and acoustic window to reach the tumor and to reach the tumor without rupturing other organs.* Recent clinical studies have shown that one of the reasons of technical failures of the RFA procedure is attributed to residual cancerous cells [28,29]. In the corresponding task boundary on the *y*-axis, the *procedure* of this milestone is explained as: *First, The US probe, the RF needle size and type is selected and, second the optimal needle trajectory is planned and the needle is navigated to target tumor.* With the guidance of US image, the clinician places the RFA needle into the center of the tumor. Before hitting the center of the tumor, the clinicians consider multiple levels of clinical constraints before locating the right entry point and navigating path. The task boundary *critical factor* on the *y*-axis is understood as: *If the trajectory is not chosen correctly, the needle does not hit the tumor in the center, causing unablated cancer cells. The ablation zone is normally taken as 5 cm. The maximum tumor size selected for ablation is 3 cm, in order to leave a safety margin of 1 cm around it.* The difficulty arises due to the fact that US image generates a 2D data, while the task of hitting the tumor is a spatial task. Additionally, while navigating the needle the information about critical anatomical structures in the part of needle navigation is not displayed in US. This missing information leads to uncertainty in performing clinical tasks.

#### 2.2.3. Verify and prioritize findings with the target user group

Results of the clinical workflow analysis serve as the basis for the development of the expert system. Each observation or clinical problem identified may not be considered critical by the clinician for developing a technological solution. It is therefore, important to get the documentation of the clinical procedures and requirements verified by the clinicians after conducting the analysis. These requirements are summarized as problem statements and clinical requirements in the future workflow of WIM. An intervention radiologist verified and prioritized the requirements corresponding to each clinical milestone that can be seen as dots placed in the selected cells of WIM (see Fig. 2).

#### 2.2.4. Communicate within a multidisciplinary development team

Results of the clinical workflow analysis need to be communicated within the multidisciplinary development team. This was done by using WIM as a communication platform during focus group sessions. Innovative ideas, current clinical trends and possible solutions (possibilities) discussed during the sessions, were documented in the future workflow component in WIM (see Fig. 2).

#### 2.2.5. Conceptualize and evaluate the design

Finally, WIM can be used to provide an overview of the assessed requirements and clinical procedures of the current clinical workflow and possible technological solutions in the future workflow. Based on the requirements several alternative concepts have been developed by generating storyboards in the multidisciplinary team. The storyboards depicting IVS design were iterated with the imaging technologists and the intervention radiologists by considering the clinical and technological bottlenecks. Based on current technical feasibility and clinical viability IVS prototype was developed.

The following sections will further explain the last two phases of the human centered design cycle: design and evaluation of the IVS.

## 3. Designing an intra-operative visualization system (IVS)

For developing an expert decision-making system two requirements are of major importance, the core technological development on the one hand and the information visualization on the other. Information visualization can be understood as real-time information provided to the clinician to assist in performing clinical tasks and decision-making. This information can originate from various sources within the clinical workspace such as planning information based on pre-operative data, real-time imaging feedback from the patient body and real-time video feedback of the robotic control system.

The IVS prototype was developed to provide information visualization during RFA to support the above mentioned two clinical milestones. The information visualization has been provided through real-time image fusion between ultrasound (US) and computerized tomography (CT). These two imaging modalities were selected for image fusion because these formats were routinely used by the intervention radiologist to perform the RFA procedure. The technology required to develop real-time image fusion is still under development [35]. Based on the current technical feasibility the IVS prototype was developed.

### 3.1. Theoretical framework: Theory of situation awareness

Similar to other complex workspaces such as aviation industry, the development of expert systems in the clinical workspace is dependent on the knowledge of factors that influence expert decision-making in complex naturalistic environments [26]. Theoretical concepts which provide an explanation on how to improve informational support of critical factors related to clinical tasks may assist in the development of better decision-making systems [15]. In this regard, the theory of situation awareness was considered relevant [36,37]. This theory had been used to design systems mainly in aviation such as, fighter aircrafts [38] and for pilot cockpits [39]. Situation awareness within complex domains involves being aware of what is happening across many aspects of the work environment. For example, while performing MIS the clinicians must be adequately aware of their location inside the patient body, and the location of critical organs in the path of the clinical tasks.

Situation awareness comprises of three main elements of cognitive processes: perception of critical factors in the environment within the given time and space, comprehension of their meaning and projection of their status into near future [40]. The three levels of situation awareness are interrelated, that means there is no comprehension without perception and hence no projected plan of action without comprehension. Thus, in order to improve decision-making in the clinical workspace all the three levels have to be considered simultaneously to realize information visualization of the IVS. The IVS should support adequate situation awareness, which is the precondition of developing an accurate mental model of the task boundaries such as, patient state and surprise state, which determine the problem solving activities (Fig. 2. Also see Appendix 1 for an explanation of these terms). This may lead to improved decision-making and hence a better task performance in the clinical workspace (Fig. 3). The following section explains how the theory of situation awareness was included in the information visualization of the IVS.

### 3.2. Design requirements

Design requirements were obtained based on the findings from the clinical workflow analysis of RFA. Table 1 illustrates how the design requirements and theoretical basis of situation awareness determined the design of information visualization in IVS. The goal of IVS is to transmit needed information to the clinician as quickly as possible and without undue cognitive effort. The IVS was designed to support three levels of situation awareness by incorporating real-time visualization inputs.

### 3.3. Information visualization in IVS

This section describes the information visualization components of the IVS designed to provide real-time image guidance to support the RFA procedure. Information visualization in the IVS was aimed to support the clinician in developing an accurate situ-

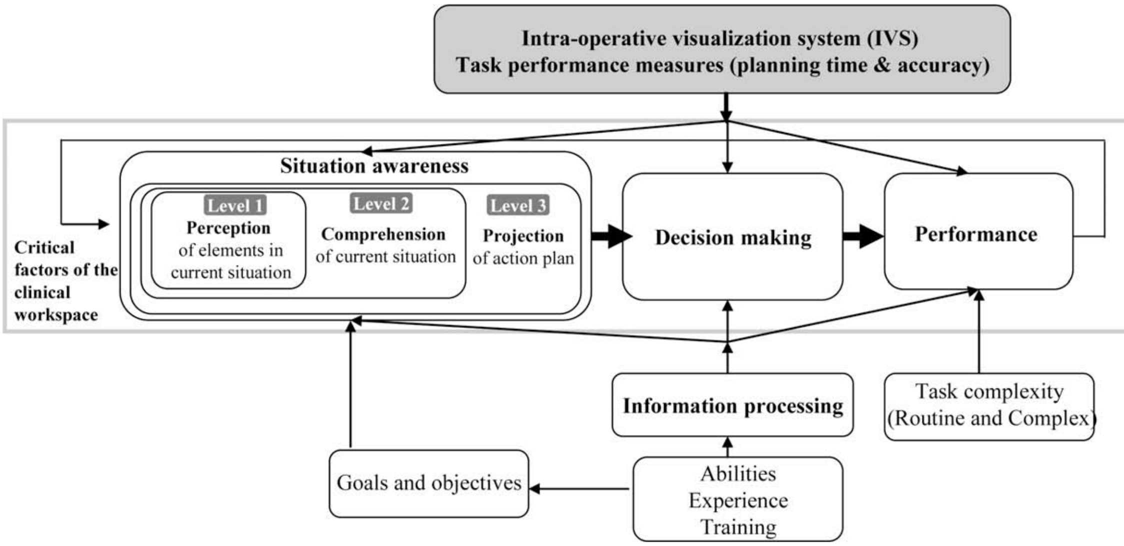


**Fig. 3.** A model of situation awareness adapted to the clinical workspace (based on the model of situated awareness of Endsley [14]).

**Table 1**
Design requirements, information visualization and situation awareness in the IVS.

| Design requirements as obtained from workflow analysis for CM 3&4 | Realization Information visualization in IVS | Theoretical basis situation awareness |
|---|---|---|
| *Visualization should support two levels of task complexity*<br>• *Routine tasks:* regular tasks conducted by the clinician in the planned way by applying the given information. In this case the ablation of the pre-operatively tumor that was planned<br>• *Complex (uncertain) tasks:* characterized by uncertainty, which means while performing clinical tasks unexpected revelations can occur. In this case the ablation of the new tumor identified in the intra-operative phase | *Visualization to support two levels of task complexity*<br>• Routine tasks: visualization support for given information, i.e. the tumor that has been planned to be ablated<br>• Complex tasks: real-time update of the intra-operative visualization in case new tumors are found during the procedure | *Visualization for two levels of task complexity*<br>Information visualization in IVS will support routine and complex tasks in order to support perception (Level 1of SA). IVS offers missing patient data and reduces noisy data causing uncertainty. This reduces ambiguity related to patient data in real-time and increases the perception and reliability of patient data. As a consequence the clinician is able to comprehend the task related complexity appropriately that supports better action planning |
| *Information visualization should be comprehensive*<br>• Integrate the information from the pre-operative into the intra-operative phase. In this case the pre-operative imaging data of the patient anatomy needs to be presented in real-time intra-operatively | *Integrated visualization of information*<br>• The pre-operative CT scan is fused with the intra-operative US. This provides the display of planning data compared to what the clinician sees in real-time | *Integrated visualization of pre-operative data in real-time*<br>IVS will visualize aggregated data and superimposition of critical information related to surgical tasks to enhance the comprehension (Level 2 of SA). The clinician mentally superimposes the pre-operative patient data from CT image to the intra-operative US data. This superimposition is done by the IVS to support the generation of the accurate mental model to enhance comprehension of patient data. On one hand IVS can reduce the cognitive load on the clinician by providing information from pre-operative stage that he/she has to carry in his head, on the other hand IVS supports generating an accurate mental model of the patient data intra-operatively |
| *Information visualization should provide critical cues to avoid ambiguity*<br>• Identify the target tumor and critical anatomical structures related to it<br>• Visualize critical anatomical cues to assist the needle navigation in the spatial space<br>• Visualize optimal trajectory of needle insertion in the percutaneous procedure | *Augmented visualization of information of critical cues*<br>• Visualization of critical cues to identify the target tumor and the vessels by providing augmented information of tumor and vessels on the US image<br>• Superimposition of pre-operative data on real-time ultrasound and visualizing the liver and anatomical structure in 3D<br>• Visualization of the liver and anatomical structure in 3D to support needle navigation<br>• Visualization of the RFA needle in 3D and its navigation in real-time | *Augmented visualization of critical cues*<br>IVS provides augmented visualization of critical cues related to clinical tasks such as needle trajectory, in order to support the clinicians' own ability to create accurate projections (Level 3 of SA). Augmented visualization means superimposition of critical cues related to the task on real-time imaging data (US). For example, anatomical cues on real-time US image to assist the needle navigation. By augmenting information of patient anatomy on the US image reduces the complexity of data. It reconfirms the critical elements related to the tasks in the US image and thus assists in non-ambiguous perception of the data. The visualization of the critical cues supports the generation of an accurate mental model of the task, thus generating a better perception, and action plan. |

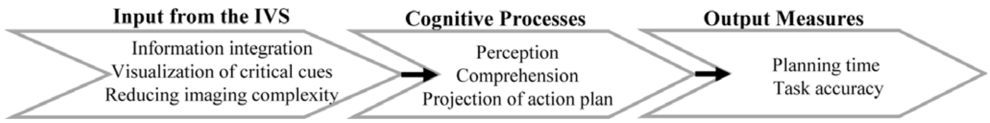


**Fig. 4.** Assumed influence of IVS on the three levels of situation awareness and on output measures.

ation awareness of the critical elements related to clinical tasks. The real-time image guidance is provided through image fusion between the two imaging modalities: ultrasound (US) and computerized tomography (CT). These imaging modalities were selected because they ranked high on the benefits from their current usage and therefore, were most trusted by the clinicians to perform the RFA procedure.

Fig. 4 illustrates the assumed influence of the information visualization from IVS on the cognitive processes and performance. It indicates that information requirements related to task boundaries as obtained from clinical workflow analysis lead to the identification of design requirements. Based on the design requirements information visualization was designed in IVS to support the three cognitive processes: perception, comprehension, and projection of action plan. The information visualized through IVS should improve the performance of the clinicians by reduced intra-operative planning time and increased task accuracy during the procedure.

Fig. 5 depicts the IVS prototype, which includes three screens to display the required information through image fusion. The combination of the three screens assisted the clinicians to identify the target tumor and aid in needle navigation. Real-time information visualization was achieved by fusion of pre-operative data obtained by CT scan with intra-operative data gained through real-time US. Task related visual cues of critical anatomical structures were augmented in 2D and 3D through image fusion between pre-operative CT and real-time data from US in Screens 1 and 2. Pre-operative CT scan of the patient was displayed in Screen 3. Together, the combination of three screens provided the required visualization to support situation awareness of the critical information in order to improve decision-making. Further details of the information visualization in the three screens are explained below:

### 3.3.1. Screen 1

Screen 1 assists the clinicians in gaining a real-time view of the patient anatomy through US guidance together with augmented information. This augmented visualization is generated through image fusion between real-time US with pre-operative CT scan. The information is augmented in 2D on the US screen. It means that only the key abstracted information related to critical structures is extracted from the pre-operative data set and is superimposed on the original US image. The system supports the decision-making in two levels of task complexities:

- Routine scenario. The image fusion provides an augmented image of the target tumor which is represented by a red arrow. As the clinicians swipes the US on the phantom, the system recognizes the target tumor due to CT and US fusion. The arrow indicates the target tumor and hence minimizes the error of selecting the wrong tumor. It provides missing patient data and reduces uncertainty caused due to noisy data of the US image. This reduces the cognitive load and hence enhances the perception of critical information. The system recognizes and tracks the location of the needle and generates a needle trajectory. The trajectory is augmented on the US image in real-time which helps in needle navigation. This may assist support the clinicians own ability to create accurate projection plan and hence improve situation awareness. The clinicians rely on US imaging for real-time data, therefore only abstracted information of critical cues is augmented on the original US image. The augmented information can be switched on and off.
- Complex scenario. Visualization in complex scenario facilitates the clinician to locate the newly detected tumor, giving opportunity to plan dynamically. The image fusion between pre-operative data and real-time US provides information about the newly detected tumor, represented by a blue arrow. This may reduce ambiguity caused by missing information and thus supports perception and comprehension.

### 3.3.2. Screen 2

This screen provides context information about the location of the tumor, the vessels and the position of the US probe. Based on image fusion between CT scan and US image, a 3D model of liver is generated. The decision-making related to positioning and guid-

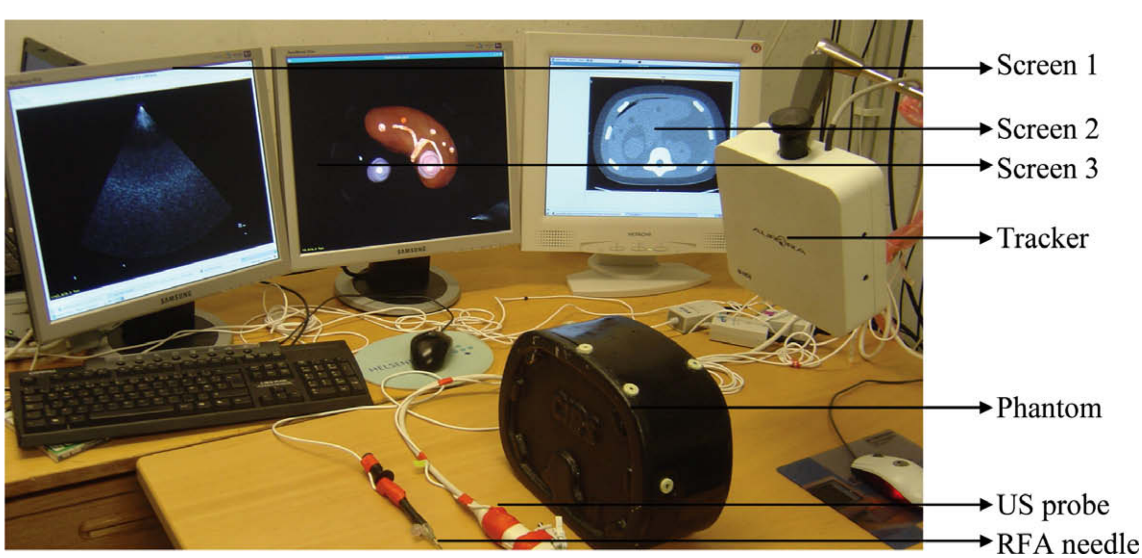


**Fig. 5.** Physical set up and components of intra-operative visualization (IVS).

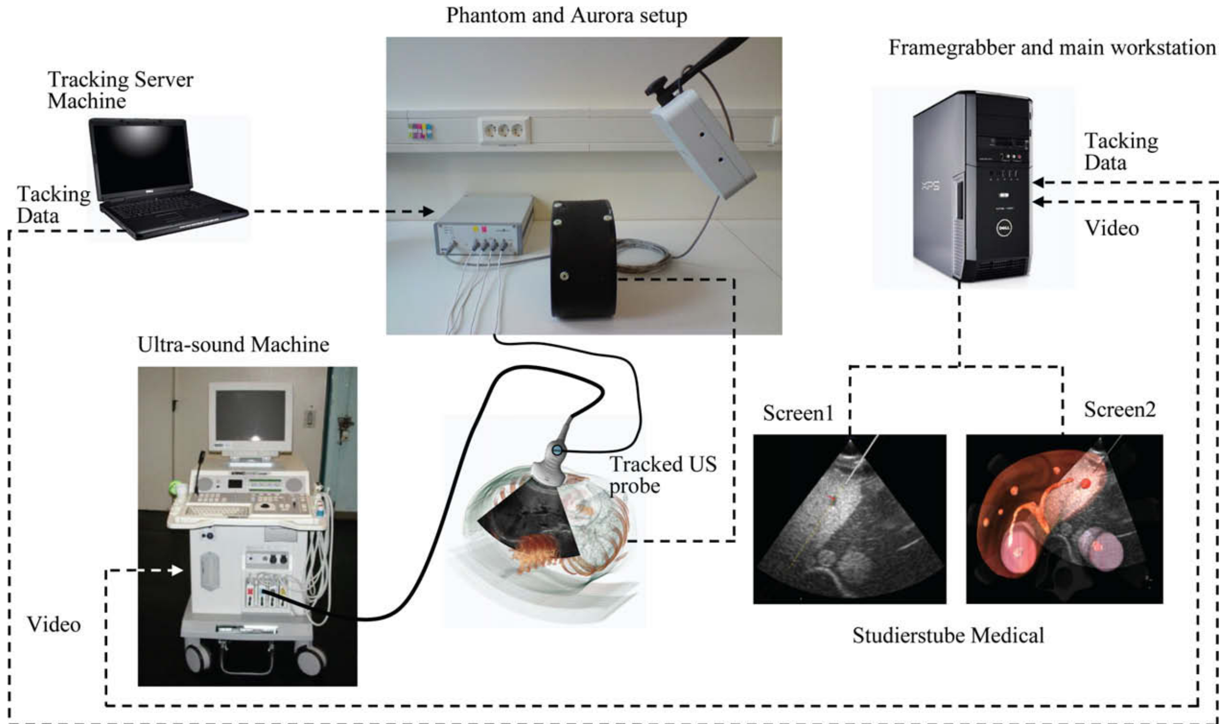


**Fig. 6.** System architecture of the IVS.

ing the needle to the center of the tumor is dependant on the anatomical and clinical constraints. The anatomical constraints for the clinical milestones 3 and 4 as identified in workflow analysis (Fig. 2) have not been considered in design due to technological limitations. The screen provides the following critical cues in both routine and complex scenarios:

- Context view. When the clinician places the needle on the phantom, Screen 2 displays the needle in a 3D model of the liver along with an augmented needle trajectory. As seen in Fig. 6 Screen 2 only shows abstract information of the 3D model of liver and not a photo realist image. This avoids information overload of the anatomical structures that are not required by the clinician for the task. This allows the clinician to have a context view of the patient anatomy and spatially orient the US probe and the needle towards the target tumor. The target tumor is marked in red in the 3D model for the routine scenario. In the complex scenario, the model updates itself and the new tumor found is marked in blue. As a consequence the clinician is able to comprehend the task related information appropriately that supports better action planning.
- Navigation and verification. The liver parenchyma, tumor and main vessels are visualized in 3D. When the clinician positions the US probe on the patient phantom, she/he knows its location corresponding to the tumor and the vessels. This assists the clinicians to place the US probe optimally and navigate the RFA needle by avoiding the anatomical structure. By visualizing critical cues related to patient anatomy IVS can aid in better perception of patient data thus supporting the situation awareness.

### *3.3.3. Screen 3*

This screen displays the original pre-operative CT scan. This is included as often during the procedure the clinicians prefer to recapitulate the overview of the patient anatomy. No additional information is augmented on the CT scan. By providing pre-operative data IVS may reduce the mental load on the clinician

### *3.3.4. System architecture*

Fig. 6 depicts the system architecture of the IVS. It includes the Aurora magnetic tracking system (Northern Digital Inc., Waterloo, Ontario) which tracks the fiducial markers on the abdominal phantom, ultrasound probe, and RF needle. Interventional 3D abdominal phantom (CIRS, Norflok, VA) has been used. The phantom was a specially made component, which constituted of a US volume of the liver and had multiple virtual tumors. It was made of jelly, which imitated the human abdomen and aided in simulating the real-world clinical condition. The main workstation used the image integration software called 'Studierstube' [22]. The software grabbed the images from the US probe and the pre-operative CT scan to generate a 3D model. Further, it integrated the tracking data from the tracking server machine to register the images and produce the video outputs in the different screens. The data were stored in the tracking server machine and the main workstation. The video input from the ultra sound machine was relayed to the tracked ultrasound probe. The pre-operative CT scan and the real-time ultrasound volume were registered and fused to display Screens 1 and 2. The data from the pre-operative CT scan were converted into a 3D model. The real-time registration of the 3D model to the ultrasound image has been simulated, however, this technology is currently being developed [41]. Functions like image zoom and rotation were provided for interact with the screens. Currently keyboard was used to activate these functions.

## 4. Evaluation of the IVS system

### *4.1. Evaluate prototype*

The evaluation of the technology robustness of the system on one hand and the clinical feasibility on the other are two different issues. Although, the technology assessment is an important issue, it is beyond the scope of this paper. The evaluation was conducted to investigate in how far the IVS supports clinical decision-making and whether it improves performance during the procedure. This study was conducted to compare, whether the IVS is better in supporting the decision-making and performance of expert intervention radiologists and medical students in comparison to the conventional ultrasound guided (USG). This is the final phase of the clinical development cycle which includes the evaluation of the IVS prototype.

### 4.2. Participants

Eight expert intervention radiologists, who were practicing RFA or biopsy procedures, were selected as participants. These experts were associated with the Rikshospitalet and Radium Hospitalet Oslo, Norway and had 8–20 years of experience in intervention radiology. It is important to mention that RFA has been recently introduced in the medical field for treating cancer of liver tumors. Therefore, the ratio of experts practicing this procedure is limited. Eight experts were the maximum number of experts available for the study in Oslo. In addition, ($n = 8$) final year medical students of the Rikshospitalet Oslo also participated in the study. All the selected student participants were required to have primary knowledge and understanding of CT scans and working with ultrasound system. This was a difficult selection to make, as the usage of both the imaging modalities is not a part of the standard education curriculum of the final year medical students. Only by personal interest, the medical students learned the usage of imaging modalities. The students had no previous training on performing RFA procedures.

### 4.3. Experimental set up

Each participant was given an hour of training time on the IVS and the US. Although, 1 h is limited time to get acquainted with IVS it was the maximum time that was available with the experts and the students. In case of students, half an hour more was kept for the training as most of them were new to performing interventions by using the US. In the training period, the participants had to perform several tasks of hitting the centre of a tumor by using both the systems. For the final task, each participant was given two tasks of hitting the center of the tumor again by using both systems. The usage of the system was alternated between the participants. First, four experts and four students were asked to perform the tasks using the US and then the IVS. This situation was reversed for the next group of participants. Two levels of task complexity routine and complex were selected. These can be further understood as:

- *Routine scenario:* This task required the participants to ablate the tumor that was selected for ablation during the pre-operative planning stage. To simulate this clinical scenario in the experiment, one of the tumors was highlighted on the CT of the abdominal phantom. The participants were required to ablate the selected tumor by using the two different systems.
- *Complex scenario:* This task required the participants to ablate the tumor which was newly detected while conducting intra-operative US. This newly detected tumour was not visible in the pre-operative CT, thus causing uncertainty in the originally planned clinical action. To simulate this complex scenario in the experiment, a tumor existing in the abdominal phantom was hidden in the CT scan. The hidden tumor was visible to the participants only while conducting the intra-operative US. The participants were expected to dynamically plan the RFA procedure.

### 4.4. Measurement

The following data were assessed to compare the output of the participants:

#### 4.4.1. Performance measures

The two main criteria selected for measuring task performance are: intra-operative planning time to execute the task and the task accuracy in hitting the center of the tumor with the RFA needle. Statistical analysis was performed using Wilcoxon signed-ranked test.

- Intra-operative task planning time. The planning time has been measured as the time taken by the participants to plan the procedure intra-operatively. This is measured as the time taken after explaining the task to the participant till the time he/she is ready to execute the task. Time to perceive and comprehend information towards deciding on an action plan is an important criterion influencing the task performance. It is a well established fact that the integration of information is an important cognitive strategy to reduce information overload [42]. It is assumed that the visualization of integrated information by IVS reduces the mental load and thus the intra-operative planning time.
- Task accuracy. Clinical findings state that the major cause of clinical errors performing the RFA procedure is either caused by the wrong tumor hit, or not hitting in the center of the tumor causing unablated cancer cells [29]. In addition to information integration, the visualization of critical cues is essential to support decision-making. Therefore, it is assumed that by providing the critical cues related to the patient's anatomy will assist the clinicians to identify and hit the right tumor in the center. As a consequence, it will improve the task accuracy and thus the clinical viability of the RFA procedure. The accuracy of hitting the center of the tumor was measured as the distance between the points of needle insertion by the participant and the mathematical center of the tumor.
- Hitting the wrong tumor. The participant's accuracy of hitting the correct target tumor during the task was measured. The wrong tumor hit was measured by the distance between the needle hit and the center of the target tumor.

#### 4.4.2. Evaluation by the participants

Subjective measures were integrated in conjunction with performance data to gain a true understanding of self reported evaluations [42]. Follow up questions were asked to each participant immediately after the study. A questionnaire with a 5 point Likert scale was used to evaluate the subjective opinion. The participants were asked to rank the visualization support and the 'felt' situation awareness obtained through both of the systems.

## 5. Results

The results from the evaluative study were analyzed in terms of performance related to intra-operative planning time and task accuracy are explained below:

### 5.1. Performance measures

#### 5.1.1. Reduced intra-operative planning time

Both the participant group's experts and students, show a significant reduction in intra-operative planning time for both levels of task complexity (routine and complex) by using IVS in comparison to the USG intervention (Table 2). The planning time of the expert participants was significantly reduced performing routine tasks ($p = 0.012$, $Med\_IVS = 2.85$ min and $Med\_USG = 6.8$ min) and complex tasks ($p = 0.036$, $Med\_IVS = 4.3$ and $Med\_USG = 5{,}62$ min). Also the planning time of the student participants was significantly reduced for routine tasks, ($p = 0.012$, $Med\_IVS = 5.39$ min and

**Table 2**
Intra-operative planning time of experts ($n = 8$) and students ($n = 8$).

| Clinicians ($n = 8$) | Planning time | | Students ($n = 8$) | Planning time | |
|---|---|---|---|---|---|
| Routine tasks | | | Routine tasks | | |
| Systems | Median | Range(min) | Systems | Median | Range(min) |
| IVS | 2.85 | 2.11–4.41 | IVS | 5.39 | 3.54–6.34 |
| USG | 6.80 | 5.54–10.27 | USG | 8.55 | 5.67–13.65 |
| Significance | $p = 0.012$ | | Significance | $p = 0.012$ | |
| Complex tasks | | | Complex tasks | | |
| Systems | Median | Range(min) | Systems | Median | Range(min) |
| IVS | 4.37 | 2.80–5.54 | IVS | 5.78 | 4.21–6.89 |
| USG | 5.62 | 4.33–7.40 | USG | 9.67 | 5.15–14.70 |
| Significance | $p = 0.036$ | | Significance | $p = 0.012$ | |

*Note:* Wilcoxon signed ranks tests ($p < 0.05$).

*Med_USG* = 8.5 min) and complex tasks ($p = 0.012$, *Med_IVS* = 5.78 - min and *Med_USG* = 9.67 min).

Results in Table 2, show that although there is a significant difference in reduced planning time between experts and students, the experts were quicker in conducting the intra-operative planning. Intra-operative planning involves not only routine tasks but also the recognition of critical situations and coping with high uncertainty [43–45]. These scenarios required to seek alternative courses of actions, which the experts are able to assemble from the repertoire accumulated during his/her past experiences [45]. This can be explained as the IVS supports the expert's experiential knowledge by providing the necessary critical cues through integrated information.

*5.1.2. Increased accuracy of hitting the tumor in the center*

The results depict that while using the IVS, experts and students show an increase in accuracy in hitting the center of the tumor as compared to the USG (Table 2). The task accuracy of hitting the center of the tumor by the expert participants did not increase significantly for the routine tasks, ($p < 0.05$, $p = 0.69$, *Med_IVS* = 2.10 mm and *Med_USG* = 2.65 mm) but increased significantly in the complex tasks, ($p = 0.017$, *Med_IVS* = 1.80 mm and *Med_USG* = 3.20 mm). The task accuracy of the student participants increased significantly while performing routine tasks, ($p = 0.025$, *Med_IVS* = 1.25 mm and *Med_USG* = 5.76 mm) and complex tasks, ($p = 0.012$, *Med_IVS* = 2.65 mm and *Med_USG* = 6.36 mm).

*5.1.3. Reduced errors in hitting the target tumor*

No wrong tumor was hit either by the experts or by the students while performing the task with the IVS. However, experts hit three wrong tumors while performing with the USG. In particular, two wrong tumor hits occurred during the routine tasks and one during the complex tasks. Student participant's hit four wrong tumors while using the USG, in which two hits were made for each task complexity.

Results (Table 3) indicate improved accuracy and reduced errors on two accounts:

First, the experts hit 3 wrong tumors and students hit 4 wrong tumors by using the US guided interventions, while there were no errors of hitting wrong tumors using the IVS. The reduced errors can be attributed to the visualized critical cues which guided the participants in selecting the target tumor.

Second, although the experts showed an overall improved accuracy in hitting the center of the tumor by using the IVS, significant differences between both systems were only found in the complex task scenario. Studies investigating problem solving in complex workspaces show that due to prior experience experts can perceive underlying causes quicker [45,46] and this high performance can hardly be improved. Therefore, no significant difference in performing routine tasks was found for experts. The students showed significant difference in achieving task accuracy of hitting the center of the tumor in both the task scenarios by using the IVS. The system supports the student's learning curve, by providing real-time visualization. Even with almost no experience of conducting the RFA procedure the students show a higher accuracy using the IVS.

*5.2. Subjective evaluation by the participants*

The participants' responses in the follow up questionnaire indicate that the situation awareness was increased using the IVS compared to the USG. Table 4 shows that experts and students rated the visualization support for intra-operative planning and creating mental models of the critical structures of patient anatomy higher in the IVS. The experts found the visualization support provided by

**Table 3**
Results: task accuracy of experts ($n = 8$) and students ($n = 8$).

| Clinicians ($n = 8$) | Task accuracy | | Students ($n = 8$) | Task accuracy | |
|---|---|---|---|---|---|
| Routine tasks | | | Routine tasks | | |
| Systems | Median | Range(mm) | Systems | Median | Range(mm) |
| IVS | 2.10 | 0.70–2.90 | IVS | 1.25 | 0.90–2.90 |
| USG | 2.65 | 2.10–12.80 | USG | 5.76 | 1.40–49.00 |
| Not Significant | $p = 0.69$ | | Significance | $p = 0.025$ | |
| Complex tasks | | | Complex tasks | | |
| Systems | Median | Range(mm) | Systems | Median | Range(mm) |
| IVS | 1.80 | 1.10–2.80 | IVS | 2.65 | 0.80–4.80 |
| USG | 3.20 | 1.90–6.80 | USG | 6.35 | 3.80–22.78 |
| Significance | $p = 0.017$ | | Significance | $p = 0.012$ | |

*Note:* Wilcoxon signed ranks tests ($p < 0.05$).

**Table 4**
Mean values of the evaluation of both systems (IVS and USG) by the participants.

| Questions | Expert ($n = 8$) | | Student ($n = 8$) | |
|---|---|---|---|---|
| | IVS | USG | IVS | USG |
| How do you rate the systems on the following parameters: | | | | |
| 1. Visualization support for Intra-operative planning | 4.00 | 3.13 | 4.50 | 2.50 |
| 2. Generating mental model of critical structures of patient anatomy | 4.50 | 3.75 | 4.38 | 2.88 |
| 3. Visualization support in routine scenarios | 3.88 | 4.25 | 4.13 | 3.00 |
| 4. Visualization support in complex scenarios | 4.13 | 3.25 | 4.50 | 3.00 |
| 5. Ability to support your performance | 4.25 | 4.00 | 4.50 | 3.35 |

*All questions used a 5-point rating scale where 5 is the most positive rating and 1 is the least positive rating.

USG better in the routine scenario. However, for complex scenarios the expert participants found the visualization improved in the IVS.

The results of the subjective evaluation (Table 4) are corresponding with the findings above (Tables 2 and 3). The findings indicate that experts found the IVS more suitable for complex scenarios than the USG. One reason might be that the IVS provides a context overview of the critical structures that supports the development of accurate situation awareness. Students benefit from using the IVS in terms of understanding the procedure and its criticalities. As an additional result it was found that the students due to lack of training in understanding US imaging found the 3D visualization of the patient anatomy beneficial in order to understand the 2D US image.

Apart from the questionnaire, the participants were also asked to share their personal experience with the system usage. It was observed that the students were quicker and more open to accept the new system than the experts. This can be explained by the quotes of five students "*IVS reminded us of playing with a video game, therefore it's easier to learn, where as the USG requires a longer time to perform the task in 2D*". The expert clinicians found the visualization provided in IVS in correspondence to their clinical workflow. Four clinicians reported, "*It is impressive as the visualization correspondence to the way I think and perform my task*". Five students and 5 clinicians reported that " *...display of pre-operative data in the intra-operative workspace assisted them in making quicker decisions*". Three expert clinicians pointed out that they required more training time "*we are so accustomed to using US that its difficult for us to adapt to 3D visualization, although the visualization aid provided seems useful*". *It would be nicer if the system is placed in our lab for a longer period so that we can get trained*".

### 5.3. Qualitative analysis

Apart from the above findings, two important observations were made while conducting the experiments.

It was observed that the participants often made a choice of conducting the task of "needle navigation" by either using Screens 1 or 2. This was an interesting observation and after the session, these participants were questioned for their choice of the screen. It was found that the choice of the screen by the participants was made based on their prior experience with the types of visualization. The experts were more accustomed to using visualization similar to Screen 1 for needle navigation and Screen 2 for a context overview. On the other hand, the medical students were more accustomed to playing video game involving 3D visualization. Thus, making it easier for them to use Screen 2 for needle navigation. For the development of IVS, it is critical that a longer training time is required in order to understand the participants' visualization preferences.

Results of the evaluative study indicate that the mean intra-operative planning time is much higher for some student participants. It was observed during the experiment that that several students took a long time to be spatially orientated. It means they had difficulties in orienting the content visualized in the screen and relating it to the patient phantom while using the US probe. Spatial cognition is central to understanding medical images, including those produced by CT, MRI, X-ray, and ultrasound. In this case proper training modules are required to train the students to understand 2D and 3D visualisation.

## 6. Summary and discussion

The paper presented the application of the workflow centered framework and its theoretical underpinning as a structured approach for designing an expert system for the clinical workspace. As an example application, the framework has been applied to develop and evaluate an intra-operative visualization system (IVS) for an upcoming minimally invasive surgery-radiofrequency ablation (RFA). Aiming to support the development of expert systems for complex work domains such as the clinical workspace, the contribution of this paper is threefold.

### 6.1. Clinical workflow analysis as structured approach to assess requirements

The first important integrative component is how cognitive processes and needs of clinicians can be analysed and incorporated in the stages of the human centered development cycle. The systematic approach of investigating the clinical requirements through the workflow integration matrix (WIM) incorporates critical clinical issues and requirements in the system design. It illustrates on what grounds the context of use/user of the system has to be selected; how the clinical procedure and requirements related to the clinical workflow have to be analyzed, validated and prioritized before communicating within a multidisciplinary development team. The framework also supports the linking between the current and future workflow to facilitate the technological development.

Clinical workflow analysis is not the final goal of the development cycle; it is all the same pivotal for acquiring the knowledge base of clinical processes and requirements, which are essential for the design and success of the system. The result of this activity should be applicable to streamline the system developmental phases and create guidelines for the development team. To analyze processes in the clinical workspace can be a challenging task for the designer. Being a non-domain expert the designer depends on the clinicians and other clinical staff for being the main informants. The information about the procedures and related problems can be gathered almost at any time from various sources. WIM provided the framework for a better understanding of the clinical problem solving processes in the surgical workspace. Designers, clinicians, and technology engineers can apply this framework to analyze the clinical procedures and requirements related to the clinical workflow.

### 6.2. Situation awareness as essential aim of information visualization

The second issue tackled in the paper is how the knowledge of the cognitive processes can be incorporated to guide information visualization in the expert system. Decision-making in intra-operative workspaces is highly dependant on developing an accurate situation awareness of the critical elements related to clinical tasks. Situation awareness is supported though improving the information visualization by offering integrated information, visualizing critical cues and augmenting information. This leads to improved perception, comprehension and action plan thereby improving decision-making of the clinicians. The results support our assumption that by visualizing the critical cues related to patient anatomy aid the clinicians' to develop better situation awareness related to identifying and hitting the center of the target tumor. The evaluation of the IVS points to an improvement of task performance of medical experts and students in comparison to the conventional approach on three outcome measures: (a) Both groups needed less intra-operative planning time, (b) they showed an increased accuracy in hitting the tumor in the center and (c) they had fewer errors in hitting the wrong tumor.

### *6.3. Safeguard the benefits of the multidisciplinary team*

During the development process, there often exist communication gaps between clinicians (clients), designers and technology engineers (developers). Communication is difficult due to ad hoc approaches and lack of a common language to exchange multidisciplinary ideas. This situation leads to a biased technological development where the clinicians are unable to adapt the new technology to the clinical workspace. The workflow centered development cycle explicitly focuses on the exchange of clinical requirements, processes, and possibilities. It is recommended that the design of system prototype should be evaluated with both, experts and novices in performing the clinical procedure. This offers the designers and technologists the opportunity to gain initial feedback from the clinicians and iterate the design to suit varied levels of expertise. This procedure would eventually lead to stronger expertise systems supporting clinical decision-making with chances of higher acceptability.

### *6.4. Limitations*

Despite of promising results of the reported study, there are also limitations to be mentioned. Currently the IVS development is at a prototype level, and has still several technological limitations in generating real-time image fusion data. For obtaining conclusive results to guide technological development requires improving the prototype at technological level and then conducting a longitudinal study with more experts from several hospitals. The following are the limitations of the present study:

- The virtual liver in the phantom consists of a few tumors and vessels. This may have made the task simpler for the clinicians, as in real life they are used to dealing with higher degree of anatomical complexities. This may have influenced the performance of the clinicians. This limitation of the phantom used in the study could be changed by developing it similar to the anatomical structure of the human liver.
- The training time in the IVS was kept the same for all the participants. Although the students had some prior experience with the US imaging, they had no experience of performing US guided procedures. This difference in knowledge level for the USG could have affected the performance of the students. This limitation can be overcomed by providing additional training time with the medical students.
- When the needle collided with the anatomical structure although there was a haptic feedback, there was no visual feedback provided on Screen 2. It means that the collision detection between the needle and the critical organ was not visualized in 3D on Screen 1. This could have created some misunderstanding in what was felt in the haptic feedback and what was displayed in screen. This limitation can be overcomed by incorporating collision detection in the 3D visualization software and motion detection.

## 7. Recommendations

The reported results allow some suggestions for developing expert decision-making systems which provide intra-operative image-guidance for clinical procedures. Information visualization is an important component of such expert systems. It is recommended that information visualization in the intra-operative workspace should mainly focus on supporting the clinician in developing an accurate situation awareness of the critical elements related to the clinical tasks. As seen in the example application, the IVS offers visualization based on real-time image fusion between two imaging modalities, intra-operative US and pre-operative CT. These are represented in three screens in a combination of 2D and 3D visualization. The screens aid in developing a context overview of the critical structures in the patient anatomy, thus helping to identify the target tumor, planning the needle trajectory and needle navigation. The systems ability to rotate 3D visualization of the critical structure and the needle trajectory in real-time, enhances the efficiency of identifying the target tumor and performing the spatial task of hitting the tumor with increased accuracy.

### *7.1. Combining 2D and 3D visualization*

Intra-operative information visualization should augment the critical cues of the patient anatomy by using a combination of 2D and 3D visualization. Both the 2D and 3D visualization complement each other by providing unique information pertaining to dynamic decision-making. It is recommended that the development of intra-operative visualization systems should consider the underlying cognitive processes by offering integrated information, visualizing critical cues and augmenting information to reduce complexity.

### *7.2. Augmentation of information*

Augmentation means that only the information related to critical structures is extracted from the pre-operative or intra-operative data set and it is superimposed on the real-time image. The augmented information of critical task related cues seems to enhance the perception and comprehension of the critical information related to performing tasks. When image fusion between two modalities occurs, new data is created. Not all the information created is relevant for the clinicians. If the clinicians are confronted with all the new information, it will increase their mental load. Based on the understanding of the cognitive processes only task specific critical cues should be augmented.

### *7.3. Selecting various imaging modalities*

Each imaging modality such as CT, US, MRI, and PET provides a unique level of information. During field studies, it was observed that clinicians rely on different imaging modalities for seeking different kinds of patient information. By removing the modality that the clinicians are trained in and by adding a new modality may lead to confusion. The current expert systems in development mainly focus on planting new technologies into the clinical workspace by disregarding the clinician's prior experience and information dependencies on the existing modalities. In case of RFA, by removing the US modality and by just providing the clinicians with fusion imaging will take away critical information for conducting the procedure. Therefore, a detailed understanding of the critical information provided by each imaging modality is required before generating fusion imaging.

### 7.4. Information integration

By visualizing integrated information (through image fusion) from the pre-operative to the intra-operative phase, IVS supports the comprehension of interrelated information that allows a quicker intra-operative planning. It also decreases mental load, as the participants were not forced to rely on his/her memory. Current visualization systems in development for RFA are mainly focused on the pre-operative planning phase, or only on the intra-operative phase, and have not yet researched on integrating the information of both phases. It is recommended that for future development of intra-operative systems the requirements in the three phases of the clinical workflow (pre-intra-post) need to be investigated and integrated. This would not only assist the clinicians in improving the overall efficiency of the procedure but also the technologists towards optimizing the software development.

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## Appendix A

Current workflow: Explanation of the task boundaries of WIM

| | |
|---|---|
| Clinical milestone | Clinical milestones are critical steps that have to be performed in order to complete the clinical procedure. Clinicians might incur certain problems while performing some of the clinical milestones. The aim of the IVS should be to support these problems in order to enhance the performance of the procedure. Clinical problems can occur for any of these clinical milestones therefore it is important to identify these correctly at the start of the workflow analysis |
| Time | Time is the duration it takes to accomplish a clinical milestone. Time also depicts the time line connecting all the three phases of the surgery which in some cases might covers days or months |
| Task boundaries | Task is the problem facing the clinician. Task boundaries are the parameters which determine the information processing activities during the clinical problem solving process. These are the key stages in which the clinician can be supported with appropriate information |
| Target state | Target state is the state into which the patient has to be taken by performing clinical action |
| *Goal* | A target to be attainted to accomplish the clinical milestone in given conditions (treatment plan and patient safety). Goals make predictions about the actions and the preconditions for those actions |
| *Procedure* | Procedure is a series of clinical actions, performed to achieve the goal. These are based on the standard clinical protocols |
| *Clinical action* | The clinical action includes steps and sub-steps that take place over time to transform the objects (procedure) into actions. The sub-steps may differ with each clinical case and are dependent on personal skill and expertise of the clinician. For creating an overview of the clinical workflow not all details of sub-steps are required till the technological approach is selected. In the later stages of the product development process, if found necessary further decomposition of the sub-steps can conducted based on HTA |
| Clinical equipment | The object that is used to perform or support clinical action |
| *Clinical tool* | Clinical tool is the equipment such as laparoscope, trocar and needle required to perform the clinical action. Set up and selection criteria of tool differ with clinical specialisation. The clinical steps, which are not effectively supported by the current tools, must be documented along with the setup and selection criteria |
| *Information system* | Clinical information system is the equipment such as intra-operative Ultrasound, Magnetic resonance imaging system and heart lung machine, that provides information about patient state, along with imaging and procedural support to the clinical action |
| Communication | Communication is the interaction between the clinician and the system or the team to receive information about the state and consequence of the clinical action |
| *Clinical equipment* | Communication between clinician and the clinical equipment is necessary to receive information about the state or consequence of the clinical action. As a response to the clinical action different systems provides critical clinical information to the clinician. For example, the clinical action includes the following steps: the ultrasound probe is placed on the patient and it guides in identifying the location of the tumour. It is important to know what information the clinician receives from the ultrasound at which angles of the probe |
| *Clinical team* | Communication between clinician and the team that is necessary to exchange information about the state or consequence of the clinical action. Clinical staff is responsible for specific clinical actions during the surgery. The stage or consequence of their action are communicated to the clinician only at critical stages. For example, during cardiac surgery at critical moments the clinician requires inputs from the heart lung machine operator or the anaesthesiologist. If this information is not conveyed on time, it might lead to serious clinical errors |
| Patient state | Is the identification of the problem related to physical form/function of the patient, that requires clinical action to improve the health of the patient. The patient state changes, as the clinical procedure progresses in time. |
| *Clinical constraint* | Constraint is the clinical (anatomical- form and function) limitation on the clinical action. The clinical system may be developed to avoid these limitations. For example, the organs in the path of the needle act as a constraint on the navigation path of the needle. This affects the selection of the entry port for the needle. A real-time knowledge of the location of the organ can help to avoid this constraint |
| *Critical factor* | Critical factor is the clinical state that has to be accomplished or avoided while performing the clinical action. For example, the critical factor for entry and placement of the needle is not to rupture other organs or vessels in the way of the needle placement. This indicates that the clinician would require certain warning or visualisation system to avoid rupturing the organs |

**Appendix A** (*continued*)

| | |
|---|---|
| *Feedback* | Feedback is the response received as a result of the clinical action. Feedback can be received from the patient body, or the system/tool in use. For example, the haptic feedback of different organs, tissues is different for different tasks |
| *Anatomical constraint* | Anatomical structure is defined as the form, function, location of the organs, tissues, bones in the patient body |
| Surprise state | Surprise state is the sudden (unexpected) revelation while performing the clinical action. This state could lead to a breakdown of the clinical procedure |
| *Uncertainty* | Uncertainty is the state of indecisiveness while performing the clinical action, raised as a consequence to the surprise state. For example, finding a new tumor in the liver, while performing an intra-operative ultrasound. Uncertainty leads to iterations in the originally planned clinical strategy |
| *New clinical strategy* | New clinical strategy is the clinical decision taken to solve the problem raised as a consequence to the surprise state. In certain cases, several other clinicians are invited into the clinical theatre and a common decision-making takes place |

Future workflow: Explanation of the categories of WIM

| | |
|---|---|
| Requirement | Requirement is the information need which is identified corresponding to the task boundary for each surgical milestone |
| *Problem statement* | Problem statement is the key problem issue, requiring a technological solution. These are also represented as problem scenarios among team members |
| *Surgical requirement* | Surgical requirement is the list of problem and wishes related to the task boundaries corresponding to each surgical milestone. These need to be verified and placed in a hierarchy by the surgeon |
| Trend | Trend is the recent development in the surgical technique or technological approach |
| *Surgical trend* | Surgical trends are various surgical techniques related to a procedure, followed in a particular surgical community or hospital or country. To compensate for the information loss in the MIS procedures surgeons try several new surgical strategies. Since many MIS procedures are very recent, surgical protocols may differ in different counties or even hospitals. It is important to select the target surgical technique at the start of the technological development. These techniques are also helpful in providing innovative ideas to guide future technological development |
| *Technological trend* | Technological trend is the global technological advancements related to addressing the surgical problem. To avoid reinventing the technology or proposing solutions, which are excessively dependent on distant technological breakthroughs, global technological trends corresponding to each surgical milestone need to be documented |
| Possibility | Alternative solutions and the development team proposed for the surgical problem |
| *Technological possibility* | Prospective technological solutions to address the surgical problem |
| *Development team* | The development group including surgeon, technologist and designer working as a team on a particular surgical problem. Different surgical issues may require different teams and each team, could be dependant on inputs from other groups |

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